FDA 510(k) Premarket Notification

K931154 EVIS 200 SYSTEM

CLEARED

Oct 7, 1993
213 days to decision

K931154 · Product code: **EOQ** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k931154/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope (flexible Or Rigid) (EOQ)
Date received	Mar 8, 1993
Decision date	Oct 7, 1993
Days to decision	213 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Corp.**
Location	Mchenry, IL, US
Contact	BARRY E SANDS
Website	https://www.olympus-global.com
510(k) history	142 submissions · 140 cleared · 1978-1995

Olympus Corp. is a Japanese optics and imaging manufacturer founded in 1919. The company operates from McHenry, US, and holds approximately 70 percent of the global endoscope market. Olympus has received FDA 510(k) clearances from total submissions between 1978 and 1995. The company's cleared devices span gastroenterology, urology, obstetrics, gynecology, and chemistry specialties. This regulatory record reflects the company's historical focus on endoscopic surgical instruments and related technologies. Notable cleared device categories include resection electrodes, fiber...